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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

MAY 24 2001

Applicant : Charles A. Vacanti, *et al.*
 Serial No. : 09/658,912

Art Unit : 1615
 Examiner : Carlos A. Azpuru

TECH CENTER 1600/2900

Filed : September 11, 2000
 Title : GUIDED DEVELOPMENT AND SUPPORT OF HYDROGEL-CELL COMPOSITIONS

Commissioner for Patents
 Washington, D.C. 20231

RESPONSE

In response to the Office action dated January 18, 2001, please consider the remarks that follow.

35 U.S.C. § 101

All of the pending claims (claims 41-44) are rejected “because the claimed invention is directed to non-statutory subject matter” (Office Action at page 2, ¶ 2). The Examiner states that these claims cover “non-statutory subject matter in that applicants are claiming a living cell” (Office Action at page 2, ¶ 2; emphasis added). This ground for rejection is respectfully traversed.

The courts have consistently held that “a living cell” is statutory subject matter. For example, in *In re Bergy*, 201 USPQ 352 (CCPA 1979), the court squarely addressed the issue of “whether an invention, otherwise patentable under the statute, is excluded from the categories of subject matter which may be patented, set forth in § 101, because it is ‘alive.’” *In re Bergy* at 357. The court found that such subject matter was not excluded. Indeed, the court stated that “[i]t is because it is alive that it is useful” (emphasis added). *In re Bergy* at 373.

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18 MAY 2001
Susan R. Jones
Susan R. Jones

The court immediately expanded on this statement by adding:

The law has long and unhesitatingly granted patent protection to new, useful, and unobvious chemical compounds and compositions in which category are to be found such important *products* of microbiological process as vitamin B-12 and adrenalin and countless other pharmaceuticals. We see no sound reason to refuse patent protection to the microorganisms themselves, or to pure microorganism cultures -- the tools used by chemical manufacturers in the same way as they use chemical elements, compounds, and compositions -- when they are new and unobvious. In fact, we see no *legally* significant difference between active chemicals which are classified as "dead" and organisms used for the *chemical* reactions which take place because they are "alive."

The subject matter of Bergy's claims is indistinguishable from the subject matter of the present claims in several important respects. First, neither Bergy's microorganisms nor Applicants' stem cells, as claimed, were genetically altered (although either could be). Second, Bergy's microorganisms and Applicants' stem cells are single cells. And third, Bergy's microorganisms and Applicants' stem cells both carry out chemically useful reactions (the isolated cells Applicants claim produce chemically useful substances (e.g. neurotransmitters) when they are implanted in, and differentiate in, a patient's body, as described in the written description at, e.g., pages 38-41). The fact that the present claims cover "a living cell" in no way renders them unpatentable.

Moreover, in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), the Supreme Court investigated congressional intent with respect to § 101 and, based on Committee Reports accompanying the 1952 Act, found that "Congress intended statutory subject matter to 'include anything under the sun that is made by man'." What is "made by man" in the instant case, and now claimed, is an isolated stem cell. These stem cells do not naturally exist in isolation, but are instead surrounded by many other cell types in a complex tissue or organism. Accordingly the cells Applicants claim are "made by man" and cannot be excluded as statutory subject matter on the ground that they are living cells. The rejection should be withdrawn.

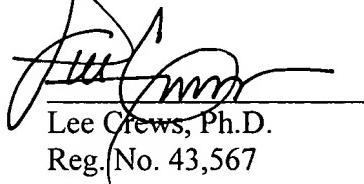
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Filed herewith is a Petition for Extension of time to extend the response period to May 18, 2001. A check for \$55.00 for the required fee is also enclosed. Any other charges, or any credits, should be applied to Deposit Account No. 06-1050.

Respectfully submitted,

Date: May 18, 2001



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